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April 11, 2005

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Art Unit: 1644

Mail Stop Amendment

Schwadron, Ronald B. Confirmation No.: 8008

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 09/350,401; Filed: July 8, 1999

For: Inducing Cellular Immune Responses to Hepatitis B Virus Using Peptide and Nucleic Acid Compositions

Inventors: SETTE et al.

Our Ref: 2060.0060008/PAJ/M-M

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Third Supplemental Information Disclosure Statement;
- 2. PTO Form 1449 citing ninety-eight (98) documents;
- 3. Copies of ninety (90) cited documents;
- 4. Fourth Supplemental Information Disclosure Statement;
- 5. PTO Form 1449 citing forty-four (44) documents;
- 6. Copies of thirty-five (35) cited documents; and
- 7. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skgf.com

Commissioner for Patents April 11, 2005 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Peter A. Jackman

Attorney for Applicants Registration No. 45,986

PAJ/M-M/slp:awt Enclosures

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Sterne, Kessler, Goldstein & Fox PLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

TTY. DOCKET NO. 2060.0060008/PAJ/M-M APPLICATION NO. 09/350,401 **FORM PTO-1449** APPLICANT(S) THIRD SUPPLEMENTAL INFORMATION DE CLOS SETTE et al. FILING DATE ART UNIT STATEMENT

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	AA100	4,2	35,877	11/25/1980	Fullerton			06/27/1979
	AB100	4,4	87,715	12/11/1984	Nitecki et al.			07/09/1982
	AC100	4,5	99,230	07/08/1986	Milich et al.			03/09/1984
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	AF100	5,1	28,319	07/07/1992	Arlinghaus			09/20/1989
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Page 2 of 26 ATTY. DOCKET NO. APPLICATION NO. 2060.0060008/PAJ/M-M 09/350,401 **FORM PTO-1449** APPLICANT(S) SETTE et al. THIRD SUPPLEMENTAL INFORMATIO **FILING DATE ART UNIT STATEMENT** July 8, 1999 1644 **U.S. PATENT DOCUMENTS EXAMINER** INITIAL DOCUMENT NUMBER DATE NAME CLASS SUB-CLASS FILING DATE AA AB AC AD ΑE AF AG AΗ ΑI ΑJ ΑK FOREIGN PATENT DOCUMENTS EXAMINER DOCUMENT NUMBER DATE COUNTRY **CLASS** SUB-CLASS TRANSLATION INITIAL Yes WO 95/07707 03/23/1995 **WIPO** AL101 No Yes 07/25/1996 **WIPO** AM101 WO 96/22067 No Yes 11/06/1997 AN101 WO 97/41440 / **WIPO** No Yes AO101 WO 97/34617 / 09/25/1997 **WIPO** No Yes WO 01/00225 01/04/2001 **WIPO** AP101 No

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FORM PTO-1449

THIRD SUPPLEMENTAL INFORMATION STATEMENT

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ATTY. DOCKET NO. 2060.0060008/PAJ/M-M APPLICANT(S) APPLICATION NO. 09/350,401

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SETTE et al.

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	AS	103		1 and HLA	ndogenous Peptides with Distinct Amino Acid Anchor Residue Motifs HLA-B8," J. Immunol. 152:620-631, American Association of					
	AT	103	Different Comb	inations of	ILA-B14 Peptide Binding Anchor Residues," <i>J. Bio</i> and Molecular Biology (19	ol. Chem. 26				
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	AR	104	Donnelly, J.J., e Inc. (April 1997		A Vaccines," Annu. Rev. II	mmunol.	<i>15</i> :61	7-648, Annu	al Reviews		
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	AS	107	Molecule HLA-	ko, E.L., et al., "Characteristics of Endogenous Peptides Eluted from the Class I MHC cule HLA-B7 Determined by Mass Spectrometry and Computer Modeling," J. nol. 151:2572-2587, American Association of Immunologists (1993)					
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	AR	110	Plasmodium fal	ciparum M	ero	Γ Helper Cell Determ zoite Surface Antigen unologists (1992)				
	AS	110	Neutralizing Do	main of HI	[ <b>V</b> -1	of Cytotoxic T Lymp by Immunization wi struct," Cell. Immunol	th an Er	ngineere	d T-Cytotox	cic-T-Helper
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Maier, R., et al., "Peptide motifs of HLA-A3, -A24, and -B7 molecules as determ pool sequencing," <i>Immunogenetics</i> 40:306-308, Springer-Verlag (1994)	nined by
AS  Martinon, F., et al., "Immunization of Mice with Lipopeptides Bypasses the Prere Adjuvant," J. Immunol. 149:3416-3422, American Association of Immunologists	
Niedermann, G., et al., "Contribution of Proteasome-Mediated Proteolysis to the I of Epitopes Presented by Major Histocompatibility Complex Class I Molecules," 2:289-299, Cell Press (1995)	
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	AR	112	Niedermann, G. and presentation	, et al., "The of antigens,"	specificity of proteasomes: in "Immunol. Rev. 172:29-48, N	npact on Iunksgaa	MHC class lard (Decemb	I processing er 1999)	
	AS	<u>112</u>	Nikolić-Žugić, J., and Carbone, F.R., "Peptide Presentation by Class-I Major Histocompatibility Complex Molecules," <i>Immunol. Res.</i> 10:54-65, S. Karger AG (1991)						
	AT	112	O'Sullivan, D., et al., "Characterization of the Specificity of Peptide Binding to Four DR Haplotypes," J. Immunol. 145:1799-1808, American Association of Immunologists (1990)						
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	AS	113	binding to huma	n MHC cla	, "Universally immuno ss II and promiscuous r gsgesellschaft mbH (198	ecognition			
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	AS	115	Immune Adjuva	nts Combin	opeptide Derivatives of Bated with or Covalently Cotal 43-352, Walter De Gruyter	upled to	Antig		
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	AR	<u>116</u>			Structure of the Human Historiol. 219:277-319, Academic P			en HLA-A2 at
	AS	<u>116</u>		o T-cell resp	tive contribution of 'determina onses," <i>Proc. Natl. Acad. Sci.</i>			
	AT	116	Schumacher, T. 706, Nature Pub		"Peptide selection by MHC cl up (1991)	ass I mo	lecules," Na	ture 350:703-
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	AR	117			HLA supertypes and : n. Immunol. 10:478-4				
	AS	117			Approach to the General 1809-1813, America				
	AT	117		MHC Clas	Conformational Propes II Molecules," <i>J. In</i> ists (1989)				
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	AR	118			Sinding to the Most nding Assays," Mod				
	AS	118		Repertoir	on of an HLA-A3-I es of Common HLA				
	AT	118			I, biochemical and of Immunol. Today 17				
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	AR	119			A-A*0207 Peptide Bindin Immunol. 58:12-20, Else				
	AS	119			r, J., "Defining rules for tl -56, Current Biology Ltd.		е-МН	C class II in	teraction,"
	AT	119			eral Common HLA-DR T amunol. 160:3363-3373, A				
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	AR	<u>120</u>			., "Properties of Purified oantigens," <i>J. Exp. Med.</i>				
	AS	120	Length and Deg	ree of Conj	ogenicity of lipid-conjugation on Induction of Aublications (1980)				
	AT	120	Steinman, R.M., Elsevier Science		cells and immune-based	I therapie	es," <i>Exp</i>	p. Hematol.	<i>24</i> :859-862,
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	AS	121	molecules from	the member	nple method to elimi rane of viable cells b ier Science (1987)				
	AT	121	synthetic peptid	le vaccines pes," <i>Proc</i>	Vaccine engineering related to hepatitis in . Natl. Acad. Sci. US	n chemically	defined	l models cor	sisting of T-
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	AS	122			s, W., "Distinct Ir Genes for I Antigen," J. Exp. Med. 150:			
	AT	122			etic Peptide Induces Long-Te 2," <i>J. Exp. Med. 165</i> :459-47			
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	AS	123	Epitope Express	sion: Respo	nduction of Virus-Specifionses Rise Steadily Until 3:3735-3745, American A	Excessive	ely Hig	gh Levels of	Epitope Are
	AT	123		I-restricte	lper epitopes enhance the d malaria peptides," <i>J. Im</i> 992)				
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	AR	<u>124</u>	Induces Antibod	lies Against	popeptide-Helper-T-Cell Epthe CTL Epitope," <i>Innovationd</i> , pp. 499-502 (1991)			
	AS	124		ontaining a p	ovel low-molecular-weight sotent B cell and macrophage			
	AT	124		ed T Lympho	J.R., "Immunodominance i ocyte Responses," <i>Annu. Rev</i>	. Immunol	. <i>17</i> :51-88, <i>I</i>	
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	AR	<u>125</u>			imary induction of virus-speci Immunol. Methods 153:193-20					
	AS	125	Zinkernagel, R.M., et al., "The Lymphoreticular System in Triggering Virus Plus Self-Specific Cytotoxic T Cells: Evidence for T Help," J. Exp. Med. 147:897-911, Rockefeller University Press (1978)							
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Confirmation No.: 8008

SETTE et al.

Art Unit: 1644

Appl. No.: 09/350,401

Examiner: Schwadron, Ronald B.

Filed: July 8, 1999

Atty. Docket: 2060.0060008/PAJ/M-M

For: Inducing Cellular Immune Responses to Hepatitis B Virus Using Peptide and Nucleic Acid

**Compositions** 

## Third Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications AA100-AH100 cited on the attached Form PTO-1449 are not submitted. Copies of all other documents are provided.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

The documents cited in this Third Supplemental Information Disclosure Statement are of general relevance to the claimed invention.

This Information Disclosure Statement is being filed before the mailing of a first Office Action. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

SETTE et al. Appl. No. 09/350,401 Atty. Docket No. 2060.0060008/PAJ/M-M

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Peter A. Jackman Attorney for Applicants Registration No. 45,986

1100 New York Avenue, N.W. Washington, D.C. 20005-3934

(202) 371-2600

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE et al.

Appl. No.: 09/350,401

Filed: July 8, 1999

For: Inducing Cellular Immune Responses to Hepatitis B Virus Using Peptide and Nucleic Acid Atty. Docket: 2060.0060008/PAJ/M-M

Examiner: Schwadron, Ronald B.

Confirmation No.: 8008

Art Unit: 1644

**Compositions** 

## **Fourth Supplemental Information Disclosure Statement**

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent

application publications, AA200-AI200, cited on the attached Form PTO-1449 are not

submitted. Copies of all other documents are provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative

submits the following discussion of the relevance of the non-English language document

AL200 cited on Form PTO-1449:

Document AL200, WO 81/00577, is in a foreign language. An English language

abstract of document AL200 is attached as document AT209.

Applicants reserve the right to establish the patentability of the claimed invention

over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the

teachings purportedly offered.

This statement should not be construed as a representation that a search has been

made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on

the material submitted herewith.

The documents cited in this Fourth Supplemental Information Disclosure

Statement generally relate to hepatitis B virus (HBV).

This Information Disclosure Statement is being filed before the mailing of a first

Office Action. No statement or fee is required.

SETTE *et al.* Appl. No. 09/350,401

Docket No.: 2060.0060008/PAJ/M-M

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Peter A. Jackman Agent for Applicants Registration No. 45,986

Date: April 11, 2005

1100 New York Avenue, N.W.

Washington, D.C. 20005-3934

(202) 371-2600

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	AA200	4,4	128,941	01/31/1984	Galibert et al.			04/30/1981	
	AB200	4,5	599,230	07/08/1986	Milich et al.			03/09/1984	
	AC200	4,5	599,231	07/08/1986	Milich et al.			03/09/1984	
	AD200	4,8	318,527	04/04/1989	Thornton et al.			12/09/1986	
	AE200	4,8	382,145	11/21/1989	Thornton et al.			10/07/1987	
	AF200	5,0	)17,558	05/21/1991	Vyas			09/13/1983	
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	AH200	5,7	783,567	07/21/1998	Hedley et al.			01/22/1997	
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			OTHER (Incl	uding Author	, Title, Date, Pertinent Pages,	etc.)			
	AR	200			Response to Pre-S2 and Hep. 24, Lancet Publishing Group		irus Induced	d Liver	
	AS	200	Barnaba, V., et al., "Recognition of Hepatitis B Virus Envelope Proteins by Liver-Infiltration T Lymphocytes in Chronic HBV Infection," J. Immunol. 143:2650-2655, American Association of Immunologists (1989)						
	AT	200	Bertoletti, A., et al., "Molecular Features of the Hepatitis B Virus Nucleocapsid T-Cell Epitope 18-27: Interaction with HLA and T-Cell Receptor," <i>Hepatology 26</i> :1027-1034, Williams & Wilkins (1997)						
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	AR	201	Proliferative and	d Cytotoxic	on of Hepatitis B Surface As Responses to a Major Annunol. 140:1808-1815, Am	tigenic Deter	minant Defin	ed by	
	AS	<u>201</u>		Cerny, A., et al., "Induction in vitro of a primary human antiviral cytotoxic T cell response," Eur. J. Immunol. 25:627-630, VCH Verlagsgesellschaft (1995)					
	АТ	201	Virus Nucleoca	Ferrari, C., et al., "Identification of Immunodominant T Cell Epitopes of the Hepatitis B Virus Nucleocapsid Antigen," J. Clin. Invest. 88:214-222, American Society for Clinical Investigation (1991)					
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	AR	<u>202</u>	Properties of Fra	agment Pep	s on Peptides. CLXVI. Stides Related to Human ene," Chem. Pharm. Bul	<b>Hepatitis</b>	B Viru	is Surface A	ntigen
	AS	202		Hopp, T.P., "Immunogenicity of a Synthetic HBsAg Peptide: Enhancement by Conjugation to a Fatty Acid Carrier," <i>Mol. Immunol. 21</i> :13-16, Pergamon Press (1984)					
	AT	202		olivet, M., et al., "Polyvalent synthetic vaccines: relationship between T epitopes and mmunogenicity," Vaccine 8:35-40, Butterworth & Co. (1990)					
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	AR	<u>203</u>	secreted (HBeA	g) form of	vaccination with plass the core protein of hep tricted epitopes," <i>Int.</i> I	atitis B vir	us prim	es T cell res	ponses to two
	AS	203	Responses In H	Livingston, B.D., et al., "Immunization with the HBV Core 18-27 Epitope Elicits CTL Responses In Humans Expressing Different HLA-A2 Supertype Molecules," Hum. Immunol. 60:1013-1017, Elsevier Science (November 1999)					
	AT	203	by Lipopeptide	ingston, B.D., et al., "The Hepatitis B Virus-Specific CTL Responses Induced in Humans Lipopeptide Vaccination are Comparable to Those Elicited by Acute Viral Infection," J. nunol. 159:1383-1392, American Association of Immunologists (1997)					
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	AR	204	Milich, D.R., "7 9:380-386, Else		ell recognition of hepatitis B vir se (1988)	al antigei	ns," <i>Immuno</i>	l. Today		
	AS	204	Response to He	Milich, D.R., and Chisari, F.V., "Immunogenetics and Cellular Correlates of the Immune Response to Hepatitis B Surface Antigen Determinants," in <i>Advances in Hepatitis Research</i> , Chisari, F.V., ed., Masson Publishing Co., New York, NY, pp. 91-109 (1984)						
	АТ	204	Single Hepatitis	Missale, G., et al., "HLA-A31- and HLA-Aw68-restricted Cytotoxic T Cell Responses to a Single Hepatitis B Virus Nucleocapsid Epitope during Acute Viral Hepatitis," J. Exp. Med. 177:751-762, Rockefeller University Press (1993)						
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	AR	205		enic Mice,'	nunobiology and Pathogen ' <i>Science 248</i> :361-364, An 1990)				
	AS	205	Hepatitis B Sur	Nayersina, R., et al., "HLA A2 Restricted Cytotoxic T Lymphocyte Responses to Multiple Hepatitis B Surface Antigen Epitopes During Hepatitis B Virus Infection," J. Immunol. 150:4659-4671, American Association of Immunologists (1993)					
	AT	205	Sequence in Co	Neurath, A.R., et al., "Specificity of Antibodies Elicited by a Synthetic Peptide Having a Sequence in Common with a Fragment of a Virus Protein-The Hepatitis B Surface Antigen," Dev. Biol. Stand. 54:103-112, S. Karger (1983)					
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	AR	<u>206</u>			of lipidated HTL-CTL of ses," <i>Vaccine 16</i> :823-83					
	AS	206	Rehermann, B., et al., "Cytotoxic T Lymphocyte Responsiveness after Resolution of Chronic Hepatitis B Virus Infection," J. Clin. Invest. 97:1655-1665, American Society for Clinical Investigation (1996)							
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	AR	207	Sällberg, M., et Epitope as a Lir	<i>al.,</i> "Huma near Detern	in and Murine B-Cell ninant," <i>Mol. Immuno</i>	ls Recognize ol. 28:719-72	the HI 6, Perg	BeAg/BETA gamon Press	(OR HBe2) (1991)
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	AR	208			ation of hepatitis B virus-sp mmon HLA class I allele in			
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